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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,408	10/01/2003	Gilbert Rene Gonzales	PEIDI-13	8069
26875 7590 04/13/2009 WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202				
			EXAMINER SAMALA, JAGADISHWAR RAO	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 04/13/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/676,408

Applicant(s)

GONZALES ET AL.

Examiner

JAGADISHWAR R. SAMALA

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-36 and 47-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-36 and 47-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment and Remarks filed on 01/13/2009.

Claims 27 and 47 have been amended.

Claims 27-36 and 47-50 are pending in the instant application.

Response to Amendment

The Declaration under 37 CFR 1.132 filed 01/13/2009 is sufficient to overcome the rejection of claim 27-36 and 47-50 based upon Robinson et al (US 6,071,539) in view of Leon Kremzner et al (US 3,012,893).

Claim Rejections - 35 USC § 112

1. Claims 27-36 and 47-50 are rejected under 35 U.S.C. 112 first paragraph, as failing to comply with the written description requirement **are withdraw** in view of applicant's arguments.

Claim Rejections - 35 USC § 102

2. Claims 27, 32-36 and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Schobel (US 4,687,662) are maintained for reasons of record in the previous office action filed on 08/13/2008.

Applicant's arguments filed on 01/13/1009 have been fully considered but they are not persuasive.

Applicant-asserts that Schobel does not disclose a gas-dispersing component including a solid matrix having at least one interior space with at least one first gas contained therein.

This is not found persuasive because in Schobel teaches effervescent compositions in the form of tablets or powders comprising a therapeutic agent, a granulating agent, a microparticulate effervescent component and additional additives such as lubricants, sweeteners and glidants and thereof would constitute towards the formation of solid matrix and further the resultant blend is then formed into effervescent tablets. The additional sweetener includes sugars such as sucrose, glucose, invert sugar, fructose, and sugar alcohols such as sorbitol, sorbitol syrup, mannitol, xylitol and the like (see col. 6, lines 25-45). Even though these additional additives are not listed as a solid matrix having a first gas, as recited in the instant claim, the same compounds (i.e. compounds that are employed to form solid matrix, the dispersing component which releases at least one first gas) would be porous enough to inherently absorb or entrap small amounts of inert gases such as air during the process of blending into effervescent tablets and thus, have the same physiochemical properties as set forth in the instant application and accordingly serve as dispersing component to release at least one first gas. And further, effervescent composition advanced by Schobel provides granulating agent along with other additives such as lubricants, antifoaming agents, flavoring agents, colorants, sweeteners and glidants may be used as is or formed into any desirable shape such as a tablet to render the composition to have interior space to

hold first gas and a gas generating effervescent component suitable for providing the necessary amount of therapeutic agent.

Gleaning from applicant's specification at page 5, lines 1-11 a first gas is generated by contact of gas-dispersing component to release or erupt gas. Thus, this component generally comprises water-soluble ingredients, such as carbohydrates, saccharides of simple sugars and sugar derivates, non-sugar sweetener, non-sweeteners, and the like. Similarly the prior art, Schobel discloses carbohydrates such as sugars, sucrose, glucose, invert sugar, fructose, and mixtures thereof; saccharin and its various salts and sugar alcohols such as sorbitol, sorbitol syrup, mannitol, xylitol, and the like (col. 6, lines 25-40). These components would be porous enough to inherently absorb or entrap small amounts of inert gases such as air during the process of blending into effervescent tablets and release the first gas in contact with water, so that Schobel discloses the first gas. The essence of dispersing a first gas and the gas generating component that reacts to produce second gas, and both gases of which are released into the liquid vehicle, will enhance distribution and dispersion of the medicament to form a clear solution. Therefore, Schobel does, not only disclose a first gas but also discloses the gas-generating effervescent component to generate a second gas.

Claim Rejections - 35 USC § 103

3. Claims 27-36 and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al (US 6,071,539) in view of Leon Kremzner et al (US 3,012,893) are withdrawn in view of applicant's arguments.

However, upon further consideration a new ground(s) of rejection is prepared as discussed below.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 27-36 and 47-50 are rejected under 35 U.S.C.103(a) as being unpatentable over First et al (US 2003/0235613 A1) in view of Wehling et al (US 5,223,264).

First discloses an oral administration form comprising an active ingredient and a pressurized gas, said pressurized gas being trapped in cavities within a pharmaceutically acceptable material, in a manner that allows its escape upon

dissolution or shattering of the administration form (0010). The oral administration form includes tablets, powder, pellets, capsule, syrup, and various candy-like forms (0020). The active ingredient includes analgesic, antipyretic agent, an anti-inflammatory agent, a vitamin, an expectorant, an antibiotic, an anti-hypertensive, etc (0015). The gas trapped materials are sugars such as glucose, fructose, sucrose, lactose, maltose, corn syrup and mixture thereof (0016). The gas trapped in the cavities may be any pharmaceutically acceptable inert gas such as carbon dioxide, nitrogen, air, helium, argon and neon (0017). Additional disclosure includes that an oral administration form may have several benefits, for instance, it may be popular with children that will like the popping sensation and will be more willing to take a popping administration form than one that does not create a popping sensation. The escape of the gas does not only produce a pleasant sensation but may also stimulate saliva production, thereby providing additional saliva to aid dissolution in the mouth and may be used to enhance dissolution of tablet or powders in a drinking liquid. Such tablets may be useful for the elderly or swallow-problem population (0018).

First meets the claim limitation but fails to include a gas-generating effervescent component therein the composition.

Wehling et al discloses an oral pediatric dosage form comprising a mixture of at least one effervescent disintegration agent (reads on gas-generating effervescent component), and a pediatrically effective amount of active ingredient, wherein said mixture is present in the form of a compressed tablet. The active ingredient include, pharmaceuticals, minerals, vitamins and dietary supplements and mixtures thereof (col.

2 lines 31-46). The effervescent disintegration agent include at least one acid selected from group consisting of citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, succinic acid and mixtures thereof, and at least one base selected from the group consisting of carbonate salts, bicarbonate salts and mixtures thereof (col. 3 lines 10-16). Additional disclosure includes that the effervescent disintegration agent is present in an amount which is effective both to aid in the rapid and complete disintegration of said tablet and to provide a positive organoleptic sensation when orally administered to children (col. 6 lines 1-5).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate one effervescent disintegration agent (reads on gas-generating effervescent component) into the First composition to aid in the rapid disintegration of effervescent tablet. The person of ordinary skill in the art would have been motivated to make these modification, because First teach that an oral administration form comprising an active ingredient and a pressurized gas, said pressurized gas being trapped in cavities upon release of gas provides additional saliva to aid dissolution in the mouth and may be used to enhance dissolution of tablet or powders in a drinking liquid. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success because both First and Wehling teaches an oral administration form (tablets) that can be used in the same field of endeavor, such as the oral administration form (tablets) may have several benefits, for instance, it may be popular with children that will like the popping sensation and will be more willing to take

a popping administration form than one that does not create a popping sensation and such tablets may be also useful for the elderly or swallow-problem population.

Conclusion

1. No claims are allowed at this time.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr